

Application No. 10/080,767
Amendment Dated March 26, 2004
Reply to Final Rejection of January 29, 2004

REMARKS/ARGUMENTS

By this Amendment, claims 1 and 23-24 are amended. Claims 1-47 are pending.

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

Entry of this Amendment is proper under 37 C.F.R. §1.116 because the Amendment: (a) places the application into condition for allowance (for reasons discussed herein), (b) does not raise any new issues requiring further search and/or consideration (because the Amendment is directed to subject matter previously considered during prosecution), (c) does not present any additional claims without canceling a corresponding number of finally rejected claims, and (d) places the application into better form for appeal, should an appeal be necessary. The Amendment was not previously made because the form of the Amendment was not determined until issuance of the Final Rejection. Applicants respectfully request entry of the Amendment.

Claim 1 is amended for improved support and to incorporate the limitations of allowed claim 23. Claim 23 is amended to recite limitations suggested by original claim 7. Claim 24, which originally recited an alternative embodiment inconsistent with original claim 23, is amended to recite limitations suggested by original claim 8.

Art Related Rejections

At the outset, Applicants note that claims 6-17, 23, 25-27, 43-44 and 46 are free of any art-related rejections, and that claims 9, 23, 25-27, 43-44 and 46 are only objected to for depending from rejected claims. Claim 1 is amended to incorporate the limitations of claim 23,

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which was acknowledged in the Final Rejection to be allowable. Therefore, claim 1 and all the claims ultimately dependent therefrom are now free of the art for at least the same reasons as original claim 23. As all the dependent claims ultimately depend from base claim 1 or 6, which are free of the art, all of the claims are free of the art.

Accordingly, reconsideration and withdrawal of all rejections under 35 U.S.C. §§ 102 and 103 are respectfully requested.

Rejection under 35 U.S.C. § 112, ¶ 2

Claims 7-8 and 10-17 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. This rejection is respectfully traversed.

(a) Recitation of "free nucleobase" in claims 7 and 8

As explained in the June 17, 2003 Amendment, the phrase "free nucleobase" is used in accordance with its conventional meaning in the art. Evidence of such convention use was provided in the form of a definition from Dorland's Illustrated Medical Dictionary.

The Final Rejection at Paragraph 6 responds:

While the examiner acknowledges Applicant[s'] definition of the term as illustrated in the Medical Dictionary, the specification does not clarify a meaning of the term and thus the term is still unclear in the context of the claim language.

This is not the appropriate standard for construing claims to analyze their compliance with Section 112. The appropriate standard is set forth in MPEP § 2111.01, which provides in pertinent part:

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When not defined by applicant in the specification, the words of a claim must be given their plain meaning. In other words, they must be read as they would be interpreted by those of ordinary skill in the art. *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001) (explaining the court's analytical process for determining the meaning of disputed claim terms).

Thus, the Final Rejection improperly requires the term at issue to be defined in the specification *in addition to* having an ordinary and accustomed meaning.

The case of *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989), cited in the Final Rejection, does not support the Examiner's position. Interpreting claims during prosecution "as broadly as their terms reasonably allow" does not mean ignoring the ordinary and accustomed meaning of a claim term. This is contrary to MPEP § 2111.01, which cites *In re Zletz* in support of the following proposition:

During examination, the claims must be interpreted as broadly as their terms reasonably allow. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification.

Thus, in the absence of a definition in the specification, the phrase "free nucleobase" must be interpreted in accordance with its conventional meaning in the art. A "free nucleobase" is simply a base lacking the sugar and phosphate group present in nucleosides and/or nucleotides. Examples of these bases are the pyrimidines uracil, cytosine and thymine, and the purines adenine and guanine. See Exhibit A, pages 512-513 of Styrer, *Biochemistry* (1981).

The Final Rejection states that "it cannot be determined . . . if a 'free nucleobase' is in reference to an extra nucleobase added to the blocking agent or a nucleobase that is different or

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distinct from the nucleobase of the target and/or probe or a base incapable of base pairing or hybridizing to the target and/or the probe.” Claim 6 clearly specifies that the blocking agent comprises at least one nucleobase conjugated to the probe and/or the target. Claim 7 specifies that the blocking agent is provided as a free base (or in a nucleoside or in a nucleotide). Therefore, the blocking agent can be, e.g., a single free base, such as thymine, that can bond with the probe and/or the target. See, e.g., the specification at Example 1, page 11, line 16 to page 13, line 2.

Accordingly, the meaning of “free nucleobase” is clear.

(b) Recitation of “1-200%” limitation in claims 10-17

As explained in the June 17, 2003 Amendment, the meaning of the percentage limitations in the phrases at issue is clear on its face, and even more so in view of the teachings in the specification.

The Final Rejection at Paragraph 8 responds:

While the examiner acknowledges Applicant[s'] arguments that the specification makes clear the meaning of the term, the courts have established that during patent examination, the claims must be interpreted broadly as reasonably allow[ed] [citing *In re Zletz*]. In this case . . . the claim as broadly written does not make clear if reference is being made to the amount of nucleobases capable of complementarity between the nucleobases of the blocking agent, probe and target or if . . . reference is being made to a length limitation of the nucleobases or if reference is being made to a molar concentration.

Firstly, interpreting the claims during prosecution “as broadly as their terms reasonably allow” does not mean ignoring the plain meaning of a claim term. See, e.g., MPEP § 2111.01.

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Neither does it mean that the teachings of the specification are to be ignored. *Id.*, citing *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) ("Claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their 'broadest reasonable interpretation'." 710 F.2d at 802, 218 USPQ at 292).

The claims recite "wherein said at least one nucleobase is provided in a quantity that is 1-200% of a number of said probe nucleobases that are Watson-Crick complements to said at least one nucleobase" and "wherein said at least one nucleobase is provided in a quantity that is 1-200% of a number of said probe nucleobases that are identical to said at least one nucleobase."

There is absolutely nothing in the plain language of the claims, or in the specification, that suggests the percentage refers to "the length of the nucleobases". The limitations at issue do not recite the term "length" or any synonym thereof.

This leaves molar quantities as the only reasonable interpretation, particularly in view of the examples provided in the specification, such as the following passage from Example 1, page 11, lines 16-19:

The 15-mer ssDNA Probe No. 1 contains six adenine bases. Conjugation of 2 pmoles of ssDNA Probe No. 1 with 3 pmoles of free thymine could result in 25% of the complementary A or 100% of the homologous T within Probe No. 1 bound to the added thymine.

There is no need to distinguish between "the amount of nucleobases capable of complementarity between the nucleobases of the blocking agent, probe and target" and "a molar concentration". When the "number of said probe nucleobases that are Watson-Crick

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complements to said at least one nucleobase" refers to molarity, the "quantity that is 1-200%" refers to molarity as well. When the "number" refers to individual probe nucleobases, the "quantity" refers to individual blocking agent nucleobases.

Accordingly, reconsideration and withdrawal of the rejection of claims 7-8 and 10-17 as being indefinite are respectfully requested.

Rejection under 35 U.S.C. § 112, ¶ 1

Claims 1 and 6 stand rejected for allegedly failing to comport with the written description requirement of 35 U.S.C. § 112, first paragraph. This rejection is respectfully traversed.

The rejection relates to language added to claim 1 by the June 17, 2003 Amendment. Contrary to the Final Rejection, said language was not added to claim 6. Claim 6 was amended to incorporate the limitations of original claim 1, not amended claim 1. Thus, claim 6 finds literal support in original claims 1 and 6, and should not have been rejected.

The language added to claim 1 by the June 17, 2003 Amendment has been deleted by this amendment.

Accordingly, reconsideration and withdrawal of the rejection of claims 1 and 6 under 35 U.S.C. § 112, first paragraph, are respectfully requested.

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

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Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

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March 26, 2004

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